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BURNS DOANE SWECKER & MATHIS L L P
POST OFFICE BOX 1404
ALEXANDRIA, VA 22313-1404

EXAMINER

HARRIS, ALANA M

| ART UNIT | PAPER NUMBER |
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1642

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DATE MAILED: 03/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/847,356

Applicant(s)

MORRIS ET AL.

Examiner

Alana M. Harris, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 and 22-24 is/are pending in the application.
- 4a) Of the above claim(s) 22-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 20 is/are rejected.
- 7) ☒ Claim(s) 18 and 19 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I (claims 1-20) in Paper No. 8, received September 26, 2002 is acknowledged.
2. Claims 1-20 and 22-24 are pending.
Claim 21 has been cancelled.
Claims 22-24, drawn to non-elected inventions are withdrawn from examination.
Claims 1-20 have been examined on the merits.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 1-16 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
 - a. The recitation "...under conditions which results in oncolysis..." in claims 1 and 20 is vague and indefinite. It is not clear what circumstances or situations would result in cell lysis.

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b. The term "complements" is vague and indefinite in claim 15. It is not art recognized that antibodies have complements. Accordingly, the metes and bounds cannot be determined.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

6. Claims 1, 5-9, 11-13 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Coffey et al. (Science 282: 1332-1334, November 13, 1998/ IDS reference). Coffey discloses a method of oncolysis of a cellular composition consisting of ras-transformed C3H-10T1/2 fibroblast tumors mediated by intratumoral injections of reovirus serotype 3 (strain Dearing), see page 1333, bridging paragraph of columns 2 and 3; page 1334, Figure 4B. Initially the tumors were formed in syngeneic immune-competent C3H mice and then they were implanted as a tumor allograft into C3H mice

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at sites overlying the left hind flank. It is reasonable to conclude that the cellular composition is a portion of tissue.

Coffey also discloses a method of oncolysis of a ras-mediated human brain glioblastoma cell line, U-87 tumor implanted into the hind flank of SCID mice, see bridging paragraph of pages 1332 and 1333. Coffey notes that "...the human glioblastoma U87 cell line overexpresses the PDGFR and thus has increased levels of activated Ras", hence the Examiner regards the formed tumor as a ras-mediated neoplasm, see page 1332, column 3, paragraph 2. Treatment with the Dearing strain of reovirus serotype 3 resulted in "[n]ecrosis of tumor cells was due to direct lysis by the virus...".

7. Claims 1, 5-9 and 11-13 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent number 6,136,307 (filed February 24, 1999/ IDS reference) as evidenced by Coffey et al. (Science 282: 1332-1334, November 13, 1998/ IDS Reference). U. S. Patent #6,136,307 discloses a method of oncolysis of a ras-mediated human brain glioblastoma cell line, U-87 tumor implanted into the hind flank of SCID mice, see column 24, lines 39-40. As noted by Coffey in the Science article "...the human glioblastoma U87 cell line overexpresses the PDGFR and thus has increased levels of activated Ras", hence the Examiner regards the formed tumor as a ras-mediated neoplasm, see page 1332, column 3, paragraph 2. Treatment with the Dearing strain of reovirus serotype 3 resulted in drastic repression of tumor growth and tumor regression, see column 13, lines 48-50; column 24, lines 47-55.

The patent also disclosed four ras-mediated pancreatic carcinoma cell lines' susceptibility to reovirus oncolysis, see column 25, line 49-60.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-7, 9-13 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coffey et al. (Science 282: 1332-1334, November 13, 1998/ IDS reference) or U.S. Patent number 6,136,307 (filed February 24, 1999/ IDS reference), in view of U.S. Patent number 6,136,307 (filed February 24, 1999/ IDS reference). The teachings of the Science article and patent have been presented above in the 102(b) and 102(e) rejections, respectively. Neither reference teaches methods to remove ras-mediated neoplastic cells from a cellular composition comprising hematopoietic stem cells harvested from bone marrow and blood suspected of containing said neoplastic cells, wherein the method comprises contacting the cellular composition with an avian reovirus under conditions which results in oncolysis of the ras-mediated neoplastic cells.

However, U.S. patent #6,136,307 does teach that a variety of solid neoplasms and hematopoietic neoplasms can be treated and non-human mammalian reoviruses such as an avian reovirus can be used, see abstract; column 6, lines 45-51; bridging paragraph of columns 7 and 8; column 8, lines 19-32. It would have been *prima facie*

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obvious to one of ordinary skill in the art at the time the claimed invention was made to treat both solid (i.e. liver, lung, pancreatic islet cells) and hematopoietic neoplasms (i.e. whole blood), as well as use an avian reovirus to mediate oncolysis. It is reasonable to conclude that both bone marrow and blood are hematopoietic structures since it is art known that both structures are capable of producing blood cells. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by teachings in the patent that suggests that either solid neoplasms or malignant tumors affecting hematopoietic structures (structures pertaining to the formation of blood cells) including components of the immune system can be treated alternatively with an avian reovirus, see column 6, lines 37-51; bridging paragraph of columns 7 and 8; column 8, lines 42-56.

10. Claims 1, 5-9, 11-13, 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coffey et al. (Science 282: 1332-1334, November 13, 1998/ IDS reference) or U.S. Patent number 6,136,307 (filed February 24, 1999/ IDS reference), in view of U.S. Patent number 5,840,502 (issued November 24, 1998).

The teachings of the Science article and patent have been presented above in the 102(b) and 102(e) rejections, respectively. Neither reference teaches a method further comprising the steps of subjecting the treated cells to a gradient, which separates the cells from the reovirus, and collecting the layer, which contains cells.

However, U.S. patent #5,840,502 teaches a method of enriching a desired cell population from cell sources utilizing a cell-trap centrifugation tube containing a specific

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density gradient solution adjusted to the specific density of a desired cell population, see abstract; columns 19 and 20. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to utilize the rapid cell enrichment method of patent '502 in the therapeutic process taught by Coffey and patent '307. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by teachings patent '502 because "[s]eparating components of biological fluids and tissues is often desirable for clinical...therapeutic applications. Therapeutically, there is a need...for purging cells or tissues intended for use in autologous cellular or tissue transfusions or transplantation, e.g. purging tissues of viral antigens and tumor cells. There is also a need for enriching or isolating desirable cells for use in transplantation, e.g. for use in ex vivo expansion of hematopoietic cells intended for allogeneic and autologous transplantation.", see column 1, lines 27-38.

Allowable Subject Matter

11. Claims 18 and 19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (703) 306-5880. The examiner can normally be reached on 6:30 am to 4:00 pm, with alternate Fridays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4315 for regular communications and (703) 308-4315 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

ALANA HARRIS
PATENT EXAMINER



Alana M. Harris, Ph.D.
December 16, 2002